

7893-01



SporAmpule® Biological Indicator, pk/20

An in-office Biological Indicator (BI) system ideal for monitoring liquid cycles and gravity steam sterilization cycles. This system requires no crushing or activation and gives clear, easy to interpret results. Purple to yellow color change or visible turbidity of a processed ampule indicates sterilizer failure. Final results are known after 48 hours incubation.

Includes: 20 Biological Indicator Ampules

The SporAmpule is a self-contained biological indicator for use with steam and washer/sterilizer processes. Each SporAmpule contains *Geobacillus stearothermophilus* spores suspended in a culture medium containing bromcresol purple acid indicator.

Instructions for Use

1. Place one or more SporAmpules in sterilizer as indicated in the sterilizer instruction manual.
2. Process the load according to the sterilizer's manufacturer's instructions.
3. After processing, open sterilizer door and allow the load to cool before removing the SporAmpules.

Monitoring Frequency

Per AAMI, ADA and CDC recommendations, Steam sterilizers should be biologically tested at least weekly, preferably daily and every load that contains an implant.

The above information is a direct transcription of information provided to MEDISCA® from the Specification Sheet and/or Certificate of Conformity provided by the manufacturer/supplier.

Incubation

1. Incubate at 55–60°C for 48 hours checking for spore growth (turbidity and/or color change from purple to yellow) at regular intervals (i.e. 12, 24, 36 hours). The SporAmpule design allows for extended incubation without fear of media evaporation.

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No color change in the purple media indicates proper sterilization.
2. Any positive (turbidity and/or color change from purple to yellow) result, should be reported immediately to a Supervisor and sterilizer taken out of service until resolved.

Use of Controls

1. As a control, an unprocessed SporAmpule (from the same lot) should be incubated each time the sterilizer is tested.

Certification

Incubate: 55 - 60°C

Storage: 2 - 8°C

Disposal: Incinerate or autoclave at 121°C
for 30 minutes or longer

Population per SporAmpule: 3.0×10^5 CFU* / 1.9 mL ampule

**D-value at 121.1°C: 1.5 minutes

***Z-value: 7.4°C (approximate, based on 118, 121.1, 124 & 132°C, exposure temperatures)

Performance Characteristics: (Based on USP Calculations)

Process	Temperature	Survives (+)	Killed (-)
Steam (Saturated)	250°F (121.1 ± 0.5°C)	5.2 minutes	14.2 minutes

* Colony forming units

** The normal resistance of the SporAmpule; i.e., the time (in minutes) to reduce the spore population by 90%. D-value determined using Fraction Negative analysis (Spearman-Karber method) and is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here. The user should determine the suitability of the SporAmpule for the intended use.

*** The number of degrees (in Celcius) to change the D-value by a factor of 10.

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